

NAPM



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NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS

320 OLD COUNTRY ROAD, GARDEN CITY, NY 11530-1752 • (516) 741-3699 FAX: (516) 741-3696

September 7, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane Rm1061
Rockville, MD 20852

RE: Draft Guidance for Industry - Average, Population, and Individual
Approaches to Establishing Bioequivalence [Docket No. 97D-0433]

NAPM is the national trade organization representing manufacturers, distributors and repackagers of generic multisource prescription drugs, OTC drugs, dietary supplements and veterinary drugs. The organization prides itself in serving the needs of its members and has been heavily involved in legislative, legal, regulatory and technical issues

We are requesting a 120 day extension of the comment period for the Draft Guidance for Industry - *Average, Population, and Individual Approaches to Establishing Bioequivalence* [Docket No. 97D-0433].

Our technical and CRO committee members are currently reviewing this document and need the additional time to provide a comment letter to your office.

Thank you for your consideration of this request.

Yours truly,

A handwritten signature in cursive script that reads "Leon Shargel".

Leon Shargel, Ph.D.
Vice President and Technical Director

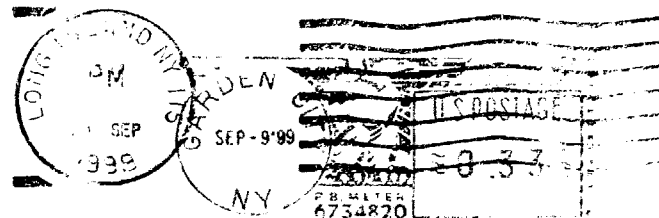
cc: Mei-Ling Chen, Ph.D.

97D-0433

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